

Substitute for form 1449A/PTO

(use as many sheets as necessary)

Complete If Known

Application Number

10/568,649

Filing Date

February 16, 2006

First Named Inventor

Georgio Terenghi

Group Art Unit

Not Yet Assigned

Examiner Name

Not Yet Assigned

Attorney Docket Number

TEPH 109


U.S. PATENT DOCUMENTS


Examiner's Signature	/Chang-Yu Wang/	Date Considered	02/02/2007
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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete If Known			
		Application Number	10/568,649		
		Filing Date	February 16, 2006		
		First Named Inventor	Georgio Terenghi		
		Group Art Unit	Not Yet Assigned		
		Examiner Name	Not Yet Assigned		
Sheet	2	of	26	Attorney Docket Number	TEPH 109

U.S. PATENT DOCUMENTS						
Examiner Initials *	Cite No. ¹	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
CYW		4,435,180		Leeper	03-06-1984	
		4,559,222		Enscore et al.	12-17-1985	
		4,573,995		Chen et al.	03-04-1986	
		4,588,580		Gale et al.	05-13-1986	
		4,603,070		Steel et al.	07-29-1986	
		4,645,502		Gale et al.	02-24-1987	
		4,648,978		Makinen, et al.	03-10-1987	
		4,664,655		Orentreich, et al.	05-12-1987	
		4,704,282		Campbell et al.	11-03-1987	
CYW		4,711,241		Lehmann	12-08-1987	

FOREIGN PATENT DOCUMENTS								
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		Office. ³	Number ⁴	Kind Code ⁵ (if known)				
CYW		EP	0 423 484		btF Biotechnologische	04-24-1991		
		EP	0 429 403		Sigma-Tau Industrie Farmaceutiche Riunite	05-29-1991		
		EP	0 432 443		Boehringer Ingelheim	06-19-1991		
		EP	0 452 111		Takeda Chemical Industries	10-16-1991		
		EP	0 507 554		Mitsui Toatsu Chemicals, Inc.	10-07-1992		
	CYW		EP	0 601 885		Takasago International Corp.	06-15-1994	

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		Number	Kind Code ² (if known)			
CYW		4,758,234		Orentreich, et al.	07-19-1988	
		4,788,062		Gale et al.	11-29-1988	
		4,792,336		Hlavacek, et al.	12-20-1988	
		4,816,258		Nedberge et al.	03-28-1989	
		4,826,493		Martini, et al.	05-02-1989	
		4,849,226		Gale	07-18-1989	
		4,856,188		Sibalis	08-15-1989	
		4,880,592		Martini, et al	11-14-1989	
		4,908,027		Enscore et al.	03-13-1990	
	CYW		4,910,145		Holmes, et al.	03-20-1990

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		Office. ³	Number ⁴	Kind Code ⁵ (if known)				
CYW		EP	0 628 586		Terumo Kabushiki Kaisha	12-14-1994		
		EP	0 754 467		Astra Aktiebolag	01-22-1997		
		EP	1130043		Canon Kabushiki Kaisha	09-05-2001		
		JP	4-326932		Nippon Zeon KK	11-16-1992		
		JP	5-023189		Mitsubishi Kasei Corp.	02-02-1993		
		JP	5-194141		Mitsubishi Kasei Corp.	11-19-1993		
	CYW		JP	7-275344		Nippon Zeon KK	10-24-1995	

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CYW		4,938,763		Dunn, et al.	07-03-1990	
		4,943,435		Baker et al.	07-24-1990	
		5,002,067		Berthelsen, et al.	03-26-1991	
		5,032,638		Wang, et al.	07-16-1991	
		5,085,629		Goldberg, et al.	02-04-1992	
		5,124,371		Tokiwa, et al.	06-23-1992	
		5,128,144		Korsatko-Wabnegg, et al.	07-07-1992	
		5,204,382		Wallace, et al.	04-20-1993	
		5,236,431		Gogolewski, et al.	08-17-1993	
CYW		5,245,023		Peoples, et al.	09-14-1993	

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		Office. ³	Number ⁴	Kind Code ⁵ (if known)				
CYW		PCT	WO 92/18164		Delta Biotech. Ltd.	10-29-1992		
		PCT	WO 93/20134		Alza Corporation	10-14-1993		
		PCT	WO 94/02184		Medinvent	02-03-1994		
		PCT	WO 94/06886		Biopak Technology, Ltd.	03-31-1994		
		PCT	WO 95/03356		Mass. Inst. of Tech.	02-02-1995		
		PCT	WO 95/20614		The Procter & Gamble Co.	08-03-1995		
CYW		PCT	WO 95/20615		The Procter & Gamble Co.	08-03-1995		

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		Number	Kind Code ² (if known)			
CYW		5,250,430		Peoples, et al.	10-05-1993	
		5,271,961		Mathiowitz, et al.	12-21-1993	
		5,278,201		Dunn, et al.	01-11-1994	
		5,278,202		Dunn, et al.	01-11-1994	
		5,278,256		Bellis	01-11-1994	
		5,292,860		Shiotani, et al.	03-08-1994	
		5,306,286		Stack, et al.	04-26-1994	
		5,334,698		Witholt, et al.	08-02-1994	
		5,468,253		Bezwada, et al.	11-21-1995	
CYW		5,480,394		Ishikawa	01-02-1996	

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		Office. ³	Number ⁴	Kind Code ⁵ (if known)				
CYW		PCT	WO 95/20621		The Procter & Gamble Co.	08-03-1995		
		PCT	WO 95/23250		The Procter & Gamble Co.	08-31-1995		
		PCT	WO 95/33874		Minnesota Mining and Manufacturing Company	12-14-1995		
		PCT	WO 96/00263		Stichting Oerzoek En Ontwikkleing Noord	01-04-1996		
		PCT	WO 96/08535		The Procter & Gamble Co.	03-21-1996		
	CYW		PCT	WO 96/18420		Bracco Research SA	06-20-1996	

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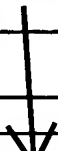
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		Number	Kind Code ² (if known)			
CYW		5,480,794		Peoples, et al.	01-02-1996	
		5,489,470		Noda	02-06-1996	
		5,502,116		Noda	03-26-1996	
		5,502,158		Sinclair et al.	03-26-1996	
		5,512,669		Peoples, et al.	04-30-1996	
		5,516,565		Matsumoto	05-14-1996	
		5,534,432		Peoples, et al.	07-09-1996	
		5,536,564		Noda	07-16-1996	
		5,550,173		Hammond, et al.	08-27-1996	
CYW		5,551,954		Buscemi, et al.	09-03-1996	

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		Office. ³	Number ⁴	Kind Code ⁵ (if known)				
CYW		PCT	WO 96/21427		Atrix Laboratories, Inc.	07-18-1996		
		PCT	WO 96/40304		Reprogenesis, Inc.	12-19-1996		
		PCT	WO 97/07153		University of Massachusetts Medical Center	02-27-1997		
		PCT	WO 97/15681		Metabolix Inc	05-01-1997		
		PCT	WO 97/30042		Global Art Co. Ltd	08-21-1997		
	CYW		PCT	WO 98/04292		Acusphere, Inc.	02-05-1998	

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		5,614,576		Rutherford et al.	03-25-1997	
		5,629,077		Turnlund, et al.	05-13-1997	
		5,625,030		Williams et al.	05-29-1997	
		5,635,215		Boschetti, et al.	06-03-1997	
		5,646,217		Hammond	07-08-1997	
		5,648,100		Boschetti, et al.	07-15-1997	
		5,670,161		Healy, et al.	09-23-1997	
		5,703,160		Dehennua et al.	12-30-1997	
CYW		5,705,187		Unger	01-06-1998	

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		Office. ³	Number ⁴	Kind Code ⁵ (if known)				
CYW		PCT	WO 98/39453		Monsanto Co.	09-11-1998		
		PCT	WO 98/48028		Monsanto Company	10-29-1998		
		PCT	WO 98/51812		Metabolix, Inc.	11-19-1998		
		PCT	WO 99/11196		Point Biomedical Corp.	03-11-1999		
		PCT	WO 99/14313		Metabolix Inc	03-25-1999		
		PCT	WO 99/32536		Metabolix, Inc.	07-01-1999		
CYW		PCT	WO 99/35192		Metabolix Inc.	07-15-1999		

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CYW ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓		5,709,854		Griffiths-Cima, et al.	01-20-1998	
		5,711,933		Bichon, et al.	01-27-1998	
		5,728,752		Scopelianos, et al.	03-17-1998	
		5,753,364		Rutherford et al.	05-19-1998	
		5,753,708		Koehler et al.	05-19-1998	
		5,811,272		Snell, et al.	09-22-1998	
		5,814,071		McDevitt, et al.	09-29-1998	
		5,814,599		Mitragotri et al.	09-29-1998	
		5,824,333		Scopelianos, et al.	10-20-1998	
	CYW		5,824,751		Hori et al.	10-20-1998

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CYW		PCT	WO 00/51662		Tepha, Inc.	09-08-2000		
↓		PCT	WO 00/56376		Metabolix, Inc.	09-28-2000		
		PCT	WO 01/15671		Tepha, Inc.,	03-08-2001		
		PCT	WO 01/19361		Tepha, Inc.	03-22-2001		
CYW		PCT	WO 04/101002		Tepha, Inc.	11-25-2004		

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CYW		5,834,582		Sinclair et al.	11-10-1998		
		5,840,331		Van Cauter, et al.	11-28-1998		
		5,842,477		Naughton, et al.	12-01-1998		
		5,855,619		Caplan, et al.	01-05-1999		
		5,876,452		Athanasios, et al.	03-02-1999		
		5,876,455		Harwin	03-02-1999		
		5,879,322		Lattin et al.	03-09-1999		
		5,919,478		Landrau et al.	07-06-1999		
		5,935,506		Schmitz, et al.	08-10-1999		
		5,990,162		Scharf	11-23-1999		
		5,994,478		Asrar et al.	11-30-1999		
		6,056,970		Greenawalt, et al.	05-02-2000		
		6,119,567		Schindler, et al.	09-19-2000		
		6,214,387		Berde, et al.	04-10-2001		
		6,245,537		Williams, et al.	06-12-2001		
		6,316,262		Huisman, et al.	11-13-2001		
		6,323,010		Skraly, et al.	11-27-2001		
		6,454,811		Sherwood, et al.	09-24-2002		
		6,514,515		Williams	02-04-2003		
		6,548,569		Williams, et al.	04-15-2003		
		6,555,123		Williams, et al.	04-29-2003		
		6,600,010		Mao, et al.	07-29-2003		
	CYW		6,610,764		Martin, et al.	08-26-2003	

Examiner's Signature	/Chang-Yu Wang/	Date Considered	02/02/2007
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		Application Number	10/568,649		
		Filing Date	February 16, 2006		
		First Named Inventor	Georgio Terenghi		
		Group Art Unit	Not Yet Assigned		
		Examiner Name	Not Yet Assigned		
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OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
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CYW		ABATE, et al., "Separation and structural characterizations of cyclic and open chain oligomers produced in the partial pyrolysis of microbial poly(hydroxybutyrate)", <i>Macromolecules</i> , 28(23):7911-1916 (1995).	
		ADDOLORATO, et al., "Maintaining abstinence from alcohol with gamma-hydroxybutyric acid", <i>The Lancet</i> , 351:38 (1998).	
		AGOSTINI, et al., "Synthesis and Characterization of Poly-B-Hydroxybutyrate. I. Synthesis of Crystalline DL Poly-B-Hydroxybutyrate from DL-B-Butyrolactone", <i>Polym. Sci. Part A-1</i> , 9:2775-87 (1971).	
		AKHTAR, "Physiomechanical Properties of bacterial PHB-HV Polyesters and Their Uses in drug Delivery", The British Library Document Supply Centre, UMI, (1990).	
		ANDERSON, et al., "Occurrence, Metabolism, metabolic Role, and Industrial Uses of bacterial Polyhydroxyalkanoates", <i>Microbiological Reviews</i> , 54(4):450-72 (1990).	
		ANDRIAMAMPANDRY, et al., "Cloning of a rat brain succinic semialdehyde reductase involved in the synthesis of the neuromodulator D-hydroxybutyrate", <i>Biochem. J.</i> , 334:43-50 (1998).	
		BAILEY, "Free radical ring-opening polymerization", <i>J. Polym. Preprints</i> , 25:210-11 (1984).	
		BAILEY, et al., "Synthesis of Poly-D-caprolactone via a free radical mechanism. Free radical ring-opening polymerization of 2-methylene-1,3-dioxepane", <i>J. Polym. Sci. Polym. Chem.</i> , 20:3021-30 (1982).	
		BANDIERA, et al., "Effect of sodium sulfonate groups on the ionic conductivity of a copolyester of thiodipropionic acid", <i>Eur. Pol. J.</i> , 33:1679-1683 (1997).	
		BEHREND, "PHB as a bioresorbable material for intravascular stents", <i>American J. Cardiol.</i> , TCT Abstracts/Oral 4S:TCT-8 (Oct. 1998).	
CYW		BERDE, et al., "Sustained release of dibucaine from a biodegradable polymer matrix: A potential method for prolonged neural blockade", Abstracts of Scientific Papers, 1990 Annual Meeting, Ameri. Soc. Anesthesiologists, 73(3A):A776, September, (1990).	
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CYW		BERGER, et al., "PHB recovery by hypochlorite digestion of non-PHB biomass", <i>Biotechnology Techniques</i> , 3(4):227-232 (1989).	
		BOEREE, et al., "Development of a degradable composite for orthopaedic use: mechanical evaluation of an hydroxyapatite-polyhydroxybutyrate composite material", <i>Biomaterials</i> , 14(10):793-6 (1993).	
		BRANDL, et al., "Pseudomonas oleovorans as a source of poly(b-hydroxyalkanoates for potential applications as biodegradable polyesters", <i>Appl. Environ. Microbiol.</i> , 54:1977-1982 (1988).	
		BRAUNEGG, et al., "Polyhydroxyalkanoates, biopolyesters from renewable resources: physiological and engineering aspects", <i>J. Biotech.</i> , 65: 127-161 (1998).	
		BREUER, et al., "Tissue Engineering Lamb Heart Valve Leaflets", <i>Biotechnology & Bioengineering</i> , 50:562-67 (1996).	
		BRUHN and MÜLLER, "Preparation and characterization of spray-dried Poly(DL-Lactide) Micro Spheres", <i>Proceed. Intern. Symp. Control. Rel. Bioact. Mater.</i> , 18:668-69 (1991).	
		BYROM, "Miscellaneous Biomaterials" in <i>Biomaterials</i> (D. Byrom, ed.) pp. 333-59 (MacMillan Publishers, London 1991).	
		CAMPBELL & BAILEY, "Mechanical properties of suture materials <i>in vitro</i> and after <i>in vivo</i> implantation in horses", <i>Vet. Surg.</i> , 21(5):355-61 (1992).	
		CHU, et al., <i>Wound Closure Biomaterials and Devices</i> CRC Press:Boca Raton, 1996.	
		COLOMBO, et al., "Involvement of GABA(A) and GABA(B) receptors in the mediation of discriminative stimulus effects of gamma-hydroxybutyric acid", <i>Physiology & Behavior</i> , 64:293-302 (1998).	
CYW		CONTI, et al., "Use of polylactic acid for the preparation of microparticulate drug delivery systems", <i>J. Microencapsulation</i> 9:153-166 (1992).	

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CYW		COOKSON, "It grows on trees", <i>Financial Times</i> , p. 6 (August 12, 1992).	
		CUEBAS, et al., "Mitochondrial metabolism of 3-mercaptpropionic acid. Chemical synthesis of 3-mercaptpropionyl coenzyme A and some of its S-acyl derivatives", <i>J. Biol. Chem.</i> , 260:7330-7336 (1985).	
		DAMIEN & PARSONS, "Bone graft and bone graft substitutes: a review of current technology and applications", <i>J. Appl. Biomater.</i> , 2(3):187-208 (1991).	
		DAYTON, et al., "Use of an absorbable mesh to repair contaminated abdominal-wall defects", <i>Arch Surg.</i> , 121:954-960 (1986).	
		DE GROOT, "Meniscal tissue regeneration in porous 50/50 copoly(L-lactide/epsilon-caprolactone) implants", <i>Biomaterials</i> , 18(8):613-22 (1997).	
		DE KONING, et al., "A biodegradable rubber by crosslinking poly(hydroxyalkanoate) from <i>Pseudomonas oleovorans</i> ", <i>Polymer</i> , 35:2090-97 (1994)	
		DE SMET, et al., "Characterization of intracellular inclusions formed by <i>Pseudomonas oleovorans</i> during growth on octane", <i>J. Bacteriol.</i> , 154:870-78 (1983).	
		DUBOIS, et al., "Macromolecular Engineering of Polylactones and Polylactides. 12. Study of the Depolymerization Reactions of Poly (-caprolactone) with Functional Aluminum Alkoxide End Groups", <i>Macromolecules</i> , 26:4407-12 (1993).	
		DUVERNOY, et al., "A biodegradable patch used as a pericardial substitute after cardiac surgery: 6- and 24-month evaluation with CT", <i>Thorac. Cardiovasc. Surg.</i> , 43(5):271-74 (1995).	
		Encyclopedic Handbook of Biomaterials and Bioengineering, Part A: Materials, Vol 1 eds. Wise, et al.; Marcel Dekker, Inc., New York, 1995.	
CYW		ENTHOLZNER, et al., "EEG changes during sedation with gamma-hydroxybutyric acid", <i>Anaesthetist</i> , 44:345-350 (1995).	

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CYW		FRASER, et al., "Controlled release of a GnRH agonist from a polyhydroxybutyric acid implant-reversible suppression of the menstrual cycle in the macaque", <i>Acta Endocrinol.</i> , 121:841-848 (1989).	
		FREED, et al., "Biodegradable polymer scaffolds for tissue engineering", <i>Biotechnology</i> , 12:689-693 (1994).	
		FÜCHTENBUSCH, et al., "Biosynthesis of novel copolyesters containing 3-hydroxypivalic acid by <i>Rhodococcus ruber</i> NCIMB 40126 and related bacteria", <i>FEMS Microbiol. Lett.</i> , 159:85-92 (1998).	
		FUKUZAKI, et al., "Direct copolymerization of L-lactic acid with γ -butyrolactone in the absence of catalysts", <i>Die Makromolekulare Chemie</i> , 190:1553-59 (1989).	
		GABBAY, et al., "New outlook on pericardial substitution after open heart operations", <i>Ann. Thorac. Surg.</i> , 48(6):803-12 (1989).	
		GAGNON, et al., "A thermoplastic elastomer produced by the bacterium <i>Pseudomonas oleovorans</i> ", <i>Rubber World</i> , 207:32-38 (1992).	
		GAGNON, et al., "Chemical modification of bacterial elastomers: 1. Peroxide crosslinking", <i>Polymer</i> , 35:4358-67 (1994).	
		GAGNON, et al., "Chemical modification of bacterial elastomers: 2. Sulfur vulcanization", <i>Polymer</i> , 35:4368-75 (1994).	
		GERNGROSS and MARTIN, "Enzyme-catalyzed synthesis of poly((R)-(-)-3-hydroxybutyrate): formation of macroscopic granules in vitro", <i>Proc. Natl. Acad. Sci. USA</i> , 92:6279-83 (1995).	
✓		GERRA, et al., "Flumazenil effects on growth hormone response to gamma-hydroxybutyric acid", <i>International Clinical Psychopharmacology</i> , 9:211-215 (1994).	
CYW		GÜRSEL, et al., "In vivo application of biodegradable controlled antibiotic release systems for the treatment of implant-related osteomyelitis", <i>Biomaterials</i> 22: 73-80 (2001).	

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CYW		HADLOCK, et al., "Ocular cell monolayers cultured on biodegradable substrates", <i>Tissue Eng.</i> , 5(3):187-96 (1999).	
		HAZARI, et al., "A new resorbable wrap-around implant as an alternative nerve repair technique", <i>J. Hand Surgery</i> , 24(3): 291-295 (1999).	
		HAZARI, et al., "A resorbable nerve conduit as an alternative to nerve autograft in nerve gap repair", <i>Br J Plast Surg.</i> , 52(8):653-7 (1999).	
		HEIN, et al., "Biosynthesis of poly(4-hydroxybutyric acid) by recombinant strains of <i>Escherichia coli</i> ", <i>FEMS Microbiol. Lett.</i> , 153:411-18 (1997).	
		HEYDORN, et al., "A new look at pericardial substitutes", <i>J. Thorac. Cardiovasc. Surg.</i> , 94:291-96 (1987).	
		HOCKING & MARCHESSAULT, "Biopolyesters" in <i>Chemistry and Technology of Biodegradable Polymers</i> , (G.J.L. Griffin, ed.), pp. 48-96, Chapman and Hall: London, 1994.	
		HOCKING & MARCHESSAULT, "Syndiotactic poly[(R,S)-β-hydroxybutyrate] isolated from methylaluminoxane-catalyzed polymerization", <i>Polym. Bull.</i> , 30:163-70 (1993).	
		HOLMES, "Biologically Produced (R)-3-hydroxyalkanoate Polymers and Copolymers", in <i>Developments in Crystalline Polymers</i> (Bassett, ed.), pp. 1-65, Elsevier: London, 1988.	
		HOLMES, et al., "Applications of PHB—a microbially produced biodegradable thermoplastic", <i>Phys Technol.</i> , 16:32-36 (1985).	
		HORI, et al., "Chemical synthesis of high molecular weight poly(3-hydroxybutyrate-co-4-hydroxybutyrate)", <i>Polymer</i> , 36:4703-05 (1996).	
CYW		HORI, et al., "Ring-Opening Copolymerization of Optically Active β-Butyrolactone with Several Lactones Catalyzed by Distannoxane Complexes: Synthesis of New Biodegradable Polyesters", <i>Macromolecules</i> , 26:4388-90 (1993).	

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CYW		HORI, et al., "Ring-Opening Polymerization of Optically Active β -Butyrolactone Using Distannoxane Catalysts: Synthesis of High Molecular Weight Poly(3-hydroxybutyrate)", <i>Macromolecules</i> , 26:5533-34 (1993).	
		HOROWITZ, et al., "Novel Thermal Route to an Amorphous, Film-Forming Polymer Latex", <i>Macromolecules</i> , 32:3347-3352 (1999).	
		HORSCH, "Inheritance of Functional Foreign Genes in Plants" <i>Science</i> , 223: 496-498 (1984).	
		HUIJBERTS, et al., "Pseudomonas putida KT2442 cultivated on glucose accumulates poly(3-hydroxyalkanoates) consisting of saturated and unsaturated monomers", <i>Appl Environ Microbiol.</i> , 58(2):536-44 (1992).	
		HUTMACHER, et al., "A review of material properties of biodegradable and bioresorbable polymers and devices for GTR and GBR applications", <i>Int. J. Oral Maxillofac. Implants</i> , 11(5):667-78 (1996).	
		KAMEYAMA, et al., "Novel sequence-ordered polymers by transformation of polymer backbone: Quantitative and regioselective insertion of Thiranes into poly(S-aryl thioester)", <i>Macromol.</i> , 32:1407-1412 (1999).	
		KASSAB, et al., "Embolization with polyhydroxybutyrate (PHB) microspheres: In vivo studies", <i>J. Bioact. Compat. Polym.</i> , 14:291-303 (1999).	
		KAUFMAN and NELSON, "An overview of gamma-hydroxybutyrate catabolism: the role of the cytosolic NADP(+) dependent oxidoreductase EC 1.1.1.19 and of a mitochondrial hydroxyacid-oxoacid transhydrogenase in the initial, rate-limiting step in this pathway", <i>Neurochemical Research</i> , 16:965-974 (1991).	
		KEELER, "Don't Let Food Go To Waste- Make Plastic Out of It", <i>R&D Magazine</i> , pp. 52-57 (1991).	
		KEELER, "Plastics Grown in Bacteria Inch Toward the Market", <i>R&D Magazine</i> , pp. 46-52 (1991).	
CYW		KEMNITZER, et al., "Preparation of predominantly Syndiotactic Poly(β -hydroxybutyrate) by the Tributyltin Methoxide Catalyzed Ring-Opening Polymerization of racemic β -Butyrolactone", <i>Macromolecules</i> , 26:1221-29 (1993).	

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CYW		KIM and MOONEY, "Engineering smooth muscle tissue with a predefined structure", <i>J. Biomed. Mat. Res.</i> , 41(2):322-332 (1998).	
		KISHIDA, et al., "Formulation-assisted biodegradable polymer matrices", <i>Chemical and Pharmaceutical Bulletin</i> , 37:1954-56 (1989).	
		KLEINSCHMIDT, et al., "Continuous sedation during spinal anaesthesia: gamma-hydroxybutyrate vs. propofol", <i>European Journal of Anaesthesiology</i> , 16:23-30 (1999).	
		KLEINSCHMIDT, et al., "Total intravenous anaesthesia using propofol, gamma-hydroxybutyrate or midazolam in combination with sufentanil for patients undergoing coronary artery bypass surgery", <i>European Journal of Anaesthesiology</i> , 14:590-599 (1997).	
		KLINGE, et al., "Functional assessment and tissue response of short- and long-term absorbable surgical meshes", <i>Biomaterials</i> , 22:1415-1424 (2001).	
		KOOSHA, "Preparation and characterization of biodegradable polymeric drug carriers", Ph.D. Dissertation, 1989, Univ. Nottingham, UK., <i>Diss. Abstr. Int.</i> , B 51:1206 (1990).	
		KOOSHA, et al., "Polyhydroxybutyrate as a drug carrier", <i>Crit. Rev. Ther. Drug Carrier Syst.</i> , 6(2):117-30 (1989).	
		KORKUSUZ, et al., <i>In vivo</i> response to biodegradable controlled antibiotic release systems, <i>J. Biomed. Mater. Res.</i> 55: 217-228 (2001).	
		KORSATKO, et al., "The influence of the molecular weight of poly-D(-)-3-hydroxybutyric acid on its use as a retard matrix for sustained drug release", <i>8th Europ. Congress of Biopharmaceutics and Pharmacokinetics</i> , 1:234-242 (1987).	
		KORTE and GELT, "Hochdruckreaktionen. II. Die Polymerisation Von γ butyrolacton und γ -valerolactam bei hohen drücken", <i>Polymer Lett.</i> , 4:685-89 (1966).	
CYW		KUSAKA, et al., "Microbial synthesis and Physical Properties of ultra-high-molecular-weight poly[(R)-3-hydroxybutyrate]", <i>Pure Appl. Chem.</i> , A35:319-35 (1998).	

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		Application Number	10/568,649		
		Filing Date	February 16, 2006		
		First Named Inventor	Georgio Terenghi		
		Group Art Unit	Not Yet Assigned		
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CYW		LAFFERTY, et al., "Microbial Production of Poly-b-hydroxybutyric acid" in <u>Biotechnology</u> (H.J. Rehm and G. Reed, eds.), Verlagsgesellschaft, Weinheim, vol. 66, pp. 135-76 (1988).	
		LAMBA, et al., "Degradation of polyurethanes", in <u>Polyurethanes in Biomedical Applications</u> (CRC Press:Boca Raton, Florida, 1998).	
		LANZA, et al., <u>Principles of Tissue Engineering</u> (Academic Press:Austin, 1997).	
		LE BORGNE and SPASSKY, "Stereoelective polymerization of β-butyrolactone", <i>Polymer</i> , 30:2312-19 (1989).	
		LEBEDEV and YEVSTROPOV, "Thermoplastic properties of polylactones", <i>Makromol. Chem.</i> , 185:1235-1253 (1984).	
		LEE, et al., "Copolymerization of γ-butyrolactone and β-butyrolactone", <i>Macromol. Chem. Phys.</i> , 198:1109-20 (1997).	
		LEMOIGNE and ROUKHELMAN, "Fermentation β-Hydroxybutyrique Caracterisation et Evolution Des Produits de Deshydratation et de Polymerisation de L'acide β-Dehydroxybutyrique", <i>Annales des fermentations</i> , 5:527-36 (1925).	
		LJUNGBERG, et al. "Neuronal survival using a resorbable synthetic conduit as an alternative to primary nerve repair", <i>Microsurgery</i> , 19(6):259-264 (1999).	
		LLOYD, et al., "Transformation of <i>Arabidopsis thaliana</i> with <i>Agrobacterium tumefaciens</i> ", <i>Science</i> , 234: 464-66 (1986).	
		LÜTKE-EVERSLÖH et al., "Identification of a new class of biopolymer: Bacterial synthesis of a sulfur-containing polymer with thioester linkages", <i>Microbiology</i> , 147(1): 11-19 (2001).	
CYW		LÜTKE-EVERSLÖH et al., "List of submitted abstracts", <i>The 8th International Symposium on Biological Polyesters</i> , (2000).	

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CYW		MADISON and HUISMAN, "Metabolic engineering of poly(3-hydroxyalkanoates): from DNA to plastic", <i>Microbiol. Molec. Biol. Rev.</i> , 63:21-53 (1999).	
		MALM, et al., "A new biodegradable patch for closure of atrial septal defect. An experimental study", <i>Scand. J. Thorac. Cardiovasc. Surg.</i> , 26(1):9-14 (1992).	
		MALM, et al., "Enlargement of the right ventricular outflow tract and the pulmonary artery with a new biodegradable patch in transannular position", <i>Eur. Surg. Res.</i> , 26(5):298-308 (1994).	
		MALM, et al., "Prevention of postoperative pericardial adhesions by closure of the pericardium with absorbable polymer patches. An experimental study", <i>J. Thorac. Cardiovasc. Surg.</i> , 104(3):600-07 (1992).	
		MARTIN and WILLIAMS, "Medical application of poly-4-hydroxybutyrate: A strong flexible absorbable biomaterial", <i>Biochem. Eng. J.</i> , 16:97-105 (2003).	
		MATHIOWITZ AND LANGER, "Polyanhydride microspheres as drug delivery systems" in <i>Microcapsules Nanopart. Med. Pharm.</i> (Donbrow, ed.), pp. 99-123 (CRC:Boca Raton, Florida, 1992).	
		MAYSINGER, "Microencapsulation and the Grafting of Genetically Transformed Cells as Therapeutic Strategies to rescue Degenerating Neurons of the CNS", <i>Reviews in the Neurosciences</i> , 6:15-33 (1995).	
		MCMILLIN, "Elastomers for Biomedical Applications", <i>Rubber Chem. Technol.</i> , 67:417-46 (1994).	
		MCWILLIAMS, "Plastics as High as an Elephant's Eye?" <i>Business Week</i> , pp. 110-11 (1991).	
		MODELLI, et al., "Kinetics of aerobic polymer degradation in soil by means of the ASTM D 5988-96 standard method", <i>J Environ Polym Degr.</i> , 7:109-116 (1999).	
CYW		MÜH, et al., "PHA synthase from chromatium vinosum: cysteine 149 is involved in covalent catalysis", <i>Bioche.</i> , 38:826-837 (1999).	

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CYW		MÜLLER, et al., "Poly(hydroxyalkanoates): A Fifth Class of Physiologically Important Organic Biopolymers", <i>Angew. Chem. Int. Ed. Engl.</i> , 32: 477-502 (1993).	
		NAKAMURA et al., "Biosynthesis and characteristics of bacterial poly(3-hydroxybutyrate-co-3-hydroxypropionate)", <i>Macromol. Rep.</i> , A28, 15-24 (1991).	
		NAKAMURA, et al., "Microbial synthesis and characterization of poly(3-hydroxybutyrate-co-4-hydroxybutyrate)", <i>Macromol.</i> , 25:4237-4241 (1992).	
		NELSON, et al., "The extraneural distribution of gamma-hydroxybutyrate", <i>J. Neurochem.</i> , 37:1345-1348 (1981).	
		NIKLASON, et al., "Functional arteries grown in vitro", <i>Science</i> , 284(5413):489-93 (1999).	
		NOBES, et al., "Polyhydroxyalkanoates: Materials for delivery systems", <i>Drug Del.</i> , 5:167-77 (1998).	
		OGAWA, et al., "A New Technique to Efficiently Entrap Leuprolide Acetate into Microcapsules of Poly Lactic Acid or Copoly(Lactic/Glycolic) Acid", <i>Chem. Pharm. Bull.</i> , 36:1095-103 (1988).	
		OTERA, et al., "Distannoxane as reverse micelle-type catalyst: novel solvent effect on reaction rate of transesterification", <i>J. Org. Chem.</i> , 54:4013-14 (1989).	
		OTERA, et al., "Distannoxane-catalysed transesterification of 1,n-Dioldiacetates. Selective transformation of either of chemically equivalent functional groups", <i>J. Chem. Soc. Chem. Commun.</i> , 1742-43 (1991).	
		OTERA, et al., "Novel distannoxane-catalyzed transesterification and a new entry to α,β -unsaturated carboxylic acids", <i>Tetrahedron Lett.</i> , 27:2383-86 (1986).	
CYW		OTERA, et al., "Novel template effects of distannoxane catalysts in highly efficient transesterification and esterification", <i>J. Org. Chem.</i> , 56:5307-11 (1991).	

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CYW		PEDRÓS-ALIO <i>et al.</i> , "The influence of poly-D-hydroxybutyrate accumulation on cell volume and buoyant density in <i>Alcaligenes eutrophus</i> ", <i>Arch. Microbiol.</i> 143:178-184 (1985).	
		PEOPLES, et al., "Poly-β-hydroxybutyrate Biosynthesis in <i>Alcaligenes eutrophus</i> H16", <i>J. Biol. Chem.</i> 264(26):15293-97 (1989).	
		PEOPLES, et al., "Polyhydroxybutyrate (PHB): A Model System for Biopolymer Engineering: II", in <i>Novel Biodegradable Microbial Polymers</i> (Dawes, ed.) pp. 191-202, Kluwer Academic Publishers: Netherlands (1990).	
		PERRIN & ENGLISH, "Polycaprolactone", in <i>Handbook of Biodegradable Polymers</i> (Domb, et al., eds.) pp. 63-77 (Harwood, Amsterdam, 1997).	
		PINTO, "Hydrogen Peroxide as depyrogenation agent for medical devices components", <i>Revista De Saude Publica</i> , 29(1):75-79 (1995).	
		POIRIER, "Perspectives on the production of polyhydroxyalkanoates in plants", <i>FEMS Microbiology Reviews</i> , 103:237-46 (1992).	
		POIRIER, et al., "Progress Toward Biologically Produced Biodegradable thermoplastics", <i>Adv. Mater.</i> , 5(1):30-37 (1993).	
		POOL, "In Search of the Plastic Potato", <i>Science</i> , 245: 1187-89 (1989).	
		POUTON and AKHTAR, "Biosynthetic polyhydroxyalkanoates and their potential in drug delivery", <i>Adv. Drug Delivery Rev.</i> , 18:133-62 (1996).	
		REHM and STEINBÜCHEL, "Biochemical and genetic analysis of PHA synthases and other proteins required for PHA synthesis", <i>Int. J. Biol. Macromol.</i> 25:3-19 (1999).	
CYW		RENSAD, et al., "The influence of processing induced differences in molecular structure on the biological and non-biological degradation of poly (3-hydroxybutyrate-co-3-hydroxyvalerate), P(3-HB-co-3-HV)", <i>Polymer Degradation and Stability</i> , 63:201-211 (1999).	

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CYW		REYNOLDS, <u>Martindale: The Extra Pharmacopeia</u> , p. 1264, (Thirty First Edition, Royal Pharmaceutical Society, London, 1997).	
		RIVARD, et al., "Fibroblast seeding and culture in biodegradable porous substrates", <i>J. Appl. Biomater.</i> , 6(1):65-68 (1995).	
		ROPERO-MILLER & GOLDBERGER, "Recreational drugs. Current trends in the 90s", <i>Clinics in Laboratory Medicine</i> , 18:727-746 (1998).	
		SABBAGH, et al., "3-Mercaptopropionic acid, a potent inhibitor of fatty acid oxidation in rat heart mitochondria", <i>J. Biol. Chem.</i> 260:7337-7342 (1985).	
		SAITO, et al., "Microbial synthesis and properties of poly(3-hydroxybutyrate-co-4-hydroxybutyrate) in <i>Comamonas acidovorans</i> ", <i>Int. J. Biol. Macromol.</i> , 16(2):99-104 (1994).	
		SCHARF, et al., "Pharmacokinetics of gammahydroxybutyrate (GHB) in narcoleptic patients", <i>Sleep</i> 21:507-514 (1998).	
		SCHLEGEL, et al., "Ein submersverfahren zur kultur wasserstoffoxydierender bakterien: Wachstumsphysiologische untersuchungen", <i>Arch. Mikrobiol.</i> 38:209-222 (1961).	
		SCHWARTZ and GOODMAN, <u>Plastic Materials and Processes</u> , (Van Nostrand Reinhold Company: New York, 1982).	
		SENDELBECK & GIRDIS, "Disposition of a 14C-labeled bioerodible polyorthoester and its hydrolysis products, 4-hydroxybutyrate and cis,trans-1,4-bis(hydroxymethyl)cyclohexane, in rats", <i>Drug Metabolism & Disposition</i> 13:291-295 (1985).	
		SHINOKA & MAYER, "New frontiers in tissue engineering: tissue engineered heart valves" in <u>Synthetic Bioabsorbable Polymer Scaffolds</u> (Atala & Mooney, eds.) pp. 187-198 Birkhäuser Boston, 1997.	
CYW		SHINOKA, et al., "Creation of viable pulmonary artery autografts through tissue engineering", <i>J. Thorac. Cardiovasc. Surg.</i> , 115(3):536-46 (1998).	

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		SIM, et al., "PHA synthase activity controls the molecular weight and polydispersity of polyhydroxybutyrate <i>in vivo</i> ", <i>Nat. Biotechnol.</i> , 15(1):63-67 (1997).	
		SKREDE et al, "Thia fatty acids, metabolism and metabolic effects" in <i>Biochim Biophys Acta</i> 1344:115-31 (1997).	
		SNEAD, "The gamma-hydroxybutyrate model of absence seizures: correlation of regional brain levels of gamma-hydroxybutyric acid and gamma-butyrolactone with spike wave discharges", <i>Neuropharmacology</i> 30:161-167 (1991).	
		SONG, et al., "Production of poly(4-hydroxybutyric acid) by fed-batch cultures of recombinant strains of <i>Escherichia coli</i> ", <i>Biotechnol. Lett.</i> 21:193-197 (1999).	
		SPEER and WARREN, "Arthroscopic shoulder stabilization. A role for biodegradable materials", <i>Clin. Orthop.</i> , (291):67-74 (1993).	
		STANTON and GAGNÉ, "The remarkable catalytic activity of alkali-metal alkoxide clusters in the ester interchange reaction", <i>J. Am. Chem. Soc.</i> , 119:5075-76 (1997).	
		STEINBÜCHEL and VALENTIN, "Diversity of bacterial polyhydroxyalkanoic acids", <i>FEMS Microbiol. Lett.</i> , 128:219-28 (1995).	
		STEINBÜCHEL and WIESE, "A <i>Pseudomonas</i> strain accumulating polyesters of 3-hydroxybutyric acid and medium-chain-length 3-hydroxyalkanoic acids", <i>Appl. Microbiol. Biotechnol.</i> , 37:691-97 (1992).	
		STEINBÜCHEL, "Polyhydroxyalkanoic Acids" in <i>Biomaterials</i> (Byrom, ed.), pp. 125-213 (MacMillan Publishers:London 1991).	
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		Application Number	10/568,649		
		Filing Date	February 16, 2006		
		First Named Inventor	Georgio Terenghi		
		Group Art Unit	Not Yet Assigned		
		Examiner Name	Not Yet Assigned		
Sheet	24	of	26	Attorney Docket Number	TEPH 109

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
CYW		TAKAGI et al., "Biosynthesis of polyhydroxyalkanoate with a thiophenoxy side group obtained from <i>Pseudomonas putida</i> ", <i>Macromolecules</i> , 32: 8315-8318 (1999).	
		TALJA, et al., "Bioabsorbable and biodegradable stents in urology", <i>J. Endourol.</i> , 11(6):391-97 (1997).	
		TANAHASHI and DOI, "Thermal Properties and Stereoregularity of Poly(3-hydroxybutyrate) Prepared from optically Active β -Butyrolactone with a Zinc-Based Catalyst", <i>Macromolecules</i> , 24:5732-33 (1991).	
		TANAKA, et al., "Clinical application of 4-hydroxybutyrate sodium and 4-butyrolactone in neuropsychiatric patients", <i>Folia Psychiatrica et Neurologica</i> 20:9-17 (1966).	
		TANGUAY, et al., "Current status of biodegradable stents", <i>Cardiol. Clin.</i> , 12(4):699-713 (1994).	
		Tepha announces submission of device master file to FDA (June 3, 2002). Retrieved 12-17-2004, from http://www.pressrelease.be/script_UK/newsdetail.asp?ndays=m&ID=695	
		Tepha submits device master file to FDA- New Technology (July 2, 2002). Retrieved on 12-17-2004, from http://www.findarticles.com/p/articles/mi_mOPC/is_7_26/ai_89018276	
		TSURUTA, et al., <i>Biomedical Applications of Polymeric Materials</i> (CRC Press, Boca Raton, Florida, 1993).	
		TUNNICLIFF, "Sites of action of gamma-hydroxybutyrate (GHB)--a neuroactive drug with abuse potential", <i>Clinical Toxicology</i> , 35:581-590 (1997).	
		TÜRESIN, et al., "Biodegradable polyhydroxyalkanoate implants for osteomyelitis therapy: <i>in vitro</i> antibiotic release," <i>J. Biomater. Sci. Polymer Edn.</i> 12: 195-207 (2001).	
CYW		TURKE, "Absorbable Biomaterial is suited for diverse applications" (06-03-2002). Retrieved on 12-17-2004, from http://www.devicelink.com/mpmn/archive/01/10/009.html	

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CYW		UNVERDORFEN, et al., "Polyhydroxybutyrate (PHB) Biodegradable Stent-Experience in the Rabbit", <i>American J. Cardiol.</i> , TCT Abstracts/Oral, p.5S:TCT-11 (Oct. 1998).	
		VALENTIN, et al., "Identification of 4-hydroxyhexanoic acid as a new constituent of biosynthetic polyhydroxyalkanoic acids from bacteria", <i>Appl. Microbiol. Biotechnol.</i> , 40:710-16 (1994).	
		VALENTIN, et al., "Identification of 5-hydroxyhexanoic acid, 4-hydroxyheptanoic acid and 4-hydroxyoctanoic acid as new constituents of bacterial polyhydroxyalkanoic acids", <i>Appl. Microbiol. Biotechnol.</i> , 46:261-67 (1996).	
		VALENTIN, et al., "Production of poly(3-hydroxybutyrate-co-4-hydroxybutyrate) in recombinant <i>Escherichia coli</i> grown on glucose", <i>J. Biotechnol.</i> , 58:33-38 (1997).	
		VON SCHROEDER, et al., "The use of polylactic acid matrix and periosteal grafts for the reconstruction of rabbit knee articular defects", <i>J. Biomed. Mater. Res.</i> , 25(3):329-39 (1991).	
		WALLEN and ROHWEDDER, "Poly-β-hydroxyalkanoate from Activated Sludge", <i>Environ. Sci. Technol.</i> , 8:576-79 (1974).	
		WIDMER and MIKOS, "Fabrication of biodegradable polymer scaffolds for tissue engineering" in <i>Frontiers in Tissue Engineering</i> (Patrick, et al., Eds.) Ch. II.5, pp.107-20 (Elsevier Science, New York, 1998).	
		WILLIAMS and PEOPLES, "Biodegradable plastics from plants", <i>Chemtech</i> , 26:38-44 (1996).	
		WILLIAMS, et al., "Application of PHAs in Medicine and Pharmacy", <i>Polyesters III</i> , 4:91-127 (2002).	
		WILLIAMS, et al., "Making plastics green", <i>Chem. Br.</i> , 33:29-32 (1997).	
CYW		WILLIAMS, et al., "PHA applications: addressing the price performance issue. I. Tissue engineering", <i>Int. J. Biol. Macromol.</i> , 25(1-3): 111-121 (1999).	

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		WONG and MOONEY, "Synthesis and properties of biodegradable polymers used as synthetic matrices for tissue engineering", in <i>Synthetic Bio degradable Polymer Scaffolds</i> (Atala, et al., eds.) pp. 51-82 (Birkhäuser: Boston, 1997).	
		WORSEY and WILLIAMS, "Metabolism of toluene and xylenes by <i>Pseudomonas putida</i> (arvilla) mt-2: evidence for a new function of the TOL plasmid" <i>J Bacteriol</i> 124:7-13 (1975).	
		XIE, et al., "Ring-opening Polymerization of β -butyrolactone by Thermophilic Lipases", <i>Macromolecules</i> , 30:6997-98 (1997).	
		YAGMURLU, et al., "Sulbactam-cefoperazone polyhydroxybutyrate-co-hydroxyvalerate (PHBV) local antibiotic delivery system: in vivo effectiveness and biocompatibility in the treatment of implant-related experimental osteomyelitis", <i>J Biomed Mater Res.</i> , 46(4):494-503 (1999).	
		YAMADA, et al., "Development of a dural substitute from synthetic bioabsorbable polymers", <i>J. Neurosurg.</i> , 86(6):1012-17 (1997).	
CYW		ZUND, et al., "The in vitro construction of a tissue engineered bioprosthetic heart valve", <i>Eur. J. Cardiothorac. Surg.</i> , 11(3):493-97 (1997).	

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